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Best practices in minimally invasive gynecology: making sense of the evidence

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Chapter 1

Introduction and thesis outline

Compared with open surgery, minimally invasive surgery (MIS) is associated with significant advantages such as decreased postoperative pain, shorter hospital stay and lower risk of (wound) infections.¹ Because of these advantages, the laparoscopic approach is nowadays often considered as the self-evident technique of many surgical procedures. Although MIS is still evolving due to the introduction of even less invasive techniques such as single port (LESS) or natural orifice surgery (NOTES), its introduction in its present form three decades ago has definitely changed daily surgical practice. MIS has even been described as the most important revolution in surgery of the last century.²

However, MIS was initially heavily criticized by surgeons who did not believe in the advantages of laparoscopy and were worried about the consequences of this complex technique. Still in 1997, in a paper published in the *Lancet*, laparoscopic surgery was defined as ‘an expensive luxury, rather than a surgical revolution’.³ Despite the criticism, MIS further developed and new instruments specifically designed for this technique were introduced (e.g. coagulation). In the twenty-first century, the implementation of advanced laparoscopic procedures drastically accelerated in all fields, including gynecology. In the Netherlands, for gynecology, this was particularly observed for laparoscopic hysterectomy (LH). In 2002, only 3% of the hysterectomies was performed laparoscopically, whereas ten years later it was 36%.⁴

With this rapid and broad introduction of MIS, external parties such as the Health Care Inspectorate (*Inspectie Gezondheidszorg*) in the Netherlands expressed in 2007 their concerns regarding patient safety during MIS. They urged for the development of a more formal quality system for surgical innovation. Yet, the introduction of new (surgical) techniques is a complex clinical dilemma in health care because of the fine line between innovation and safety. In general, the true impact of new surgical techniques can only be appreciated after a certain period of time, once the learning curve has been completed and experience has been gained. Nevertheless, it goes without saying that patient safety should be assured at all time, regardless of the surgical experience. In contrast to the introduction of new medication, techniques and devices are often introduced without extensive evaluation of efficacy and safety. In Europe, a *Conformité Européenne (CE) Marking* is sufficient to place a product on the market. Yet, this CE approval does not guarantee sufficient clinical evidence. Finally, doctors, but also patients, often presume that a new technique is per definition better than the previous one. This enthusiasm for new technology has in the past regularly outstripped evidence.⁶

Because of the above-mentioned challenges faced in the field of surgery, many guidelines have been written over the years describing how to properly implement and assess new techniques and devices. In 2009, a British research group published in the *Lancet* the IDEAL recommendations (Idea, Development, Exploration, Assessment, Long-term follow-

up).⁷ This framework was the first one specifically established for surgical innovations. The authors of the IDEAL group described five stages through which every surgical innovation should go, from the proof of concept up to the long-term evaluation. This framework emphasizes firstly, that surgical innovations should be prospectively evaluated, secondly, that the outcome measures should be predefined and include the learning curves of the surgeons and finally, that the efficacy of the innovation should be by preference assessed through randomized controlled trials. Similarly, in 2012 in the Netherlands, a report was published on how to assure patient safety in the hospital.⁸ The report recommended hospitals to perform a *Prospective Risk Inventory* (PRI) using for example the Health Care Failure Mode and Effect Analysis (HFMEA) method for high risk health care processes such as a surgery.⁹ Rather than focusing on adverse events that have already occurred, the HFMEA method aims to identify potential risks by evaluating a health care process in a systematic way and most importantly before its implementation.⁹

Looking specifically at the introduction of MIS in gynecology, it can be assumed that in general this technique has not been introduced in every hospital according to the guidelines as described in previous paragraph. Although it is unrealistic that methods or tools such as IDEAL or HFMEA would foresee every risk, it seems that for certain instruments or techniques within MIS the introduction could have been better. In addition, as advanced procedures in MIS have been introduced so rapidly, it is also probable that surgeons have developed policies based on their own expert-opinion. Although it is questionable if (small) clinical variations between hospitals always negatively influence patient outcomes, it feels conflicting that in an era of evidence-based medicine, patient's care depends to a certain extent on the hospital where the patient is treated. To discard unwanted practice variations, the development of a best practice guideline is a first step. Govaerts et al. already demonstrated that for colorectal surgery standardization of care at a national level resulted in better outcomes and simultaneously in a decrease in costs.¹⁰ Particularly for MIS, it is interesting to formulate national recommendations that are specifically tailored to this technique. Indeed, in many hospitals, protocols from open surgery are also applied to MIS procedures, and this potentially counteracts with the advantages associated with this less invasive approach.

Aim of the thesis

MIS is still a relatively young surgical specialty that has rapidly been adopted over the past decades. As such, we hypothesized that many aspects of this surgical technique are based on limited scientific support. In an era of evidence-based medicine, these expert-

based medical practices should be addressed. The aim of this thesis is to identify clinically relevant topics within the field of MIS and to formulate best practices for them.

Firstly, we focused on the most performed advanced procedures in MIS in gynecology: the LH. The ultimate goal was to cover all (technical) aspects of LH to allow for a uniform implementation of this procedure in the field of gynecology. As such, an evidence-based guideline providing insight into the best practice for LH was developed in collaboration with the Dutch Society of Endoscopic Surgery (WGE), a working group of the Dutch Society of Obstetrics and Gynecology (NVOG). In addition, various clinical topics related to LH that were found to be based on limited evidence were further studied. With this research, we aim to close specific knowledge gaps of LH encountered in daily practice.

Secondly, we concentrated in this thesis on the laparoscopic myomectomy (LM). Although LM has been recognized to be safe and effective, this procedure remains technical challenging. We specifically aim to get insight into the limits of this new technique and to evaluate its relative efficacy compared to other uterine-sparing treatment options for fibroids. To determine the benefits of the different approaches, we primarily evaluated outcomes that were directly relevant for patients.

In healthcare, it has been broadly recognized that the opinion and experiences of patients are of added value when evaluating the provided care. Over the past decade, tools such as patient reported outcome measures (PROMs) have been introduced in most medical fields. In this light, in the finale part of the thesis, we evaluated aspects of MIS from patient's perspectives.

Thesis outline

In the first part of this thesis, clinically relevant topics related to laparoscopic hysterectomy (LH) are discussed. To start, a guideline for LH was developed to standardize daily practice of this procedure. In **chapter 2** the clinical recommendations of this guideline are summarized. In **chapter 3** to **chapter 7**, specific issues related to LH and based on limited evidence are further studied.

In **chapter 3**, the surgical outcomes of LH are compared to vaginal hysterectomy (VH). VH has been demonstrated to be the technique of first choice for surgical removal of the uterus. Yet, looking at the increasing numbers of LHs performed at the expense of VH, re-evaluation of the two techniques based on recent literature is necessary. Similarly, in an effort to extend the benefits of minimally invasive surgery, an enthusiasm for the laparoendoscopic single site surgery (LESS) has emerged. In **chapter 4**, the literature is reviewed to determine if LESS for hysterectomy has added value over the conventional laparoscopic approach from a safety and efficacy point of view.

The utility of routine cystoscopy after hysterectomy is another controversial topic studied in this thesis. Standard cystoscopy has been recommended after hysterectomy to detect intra-operative ureter injuries. In **chapter 5** the additional value of this policy is being evaluated based on a large retrospective cohort.

The best timing to remove the indwelling urinary catheter after uncomplicated LH also remains unclear and not well-studied. To define the best moment to remove the catheter, nurses were asked to give their opinion on catheter management after LH. Also, we evaluated the standard indwelling catheter policy after LH in all Dutch hospitals. The data of both topics are presented in **chapter 6**. In addition, a randomized controlled trial was performed to evaluate if direct catheter removal is associated with similar (or better) outcomes compared to delayed removal. The results are given in **chapter 7**.

In the second part of this thesis, the laparoscopic myomectomy (LM) procedure is assessed. Myomectomy has typically been the first choice for surgical treatment of fibroids and with the advances of MIS, more procedures are being performed laparoscopically. In **chapter 9**, the limits of LM are explored by evaluating the risk of conversion. To extract uterine fibroids during LM, (power) morcellation was introduced in the field of MIS. Since the use of power morcellation was discouraged in 2014, contained morcellation has been proposed as the solution and this technique has been widely adopted. However, from an oncological point of view, the safety of this in-bag morcellation technique during myomectomy can be questioned. To assess the presence of spill after myomectomy, peritoneal washings were performed. In **chapter 8**, the results of these peritoneal washings were described.

For women requiring surgical treatment but desiring uterine conservation, a wide range of MIS options are available besides myomectomy. However, limited information exists on relative efficacy of these uterine-sparing treatment options. In **chapter 10**, different minimally invasive treatment options for fibroids are compared in terms of re-intervention risk and quality of life.

In the final part of this thesis, aspects from patient's perspectives are assessed. Patient's perspectives are being increasingly considered when determining the best care. In this light, data on medical liability are an interesting complementary source for that purpose as it gives a unique insight into care judged by patients as being substandard. In **chapter 12**, the medical claims of laparoscopic procedures in gynecology are analyzed and specifically trends and/or risk factors associated with these claims are identified. In **chapter 11**, the postoperative period at home was evaluated for patients undergoing laparoscopic surgery. As these patients tend to have a short hospital stay and recovery mostly at home, the postoperative period at home needs to be well-organized. In **chapter 11**, suggestions are made to facilitate a quick recovery and avoid unnecessary delay when complications occur.

Finally, **chapter 13** and **chapter 14** provide the general discussion including future research perspectives as well as a summary of this thesis (in Dutch and English).

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